

## **Tab 2**

### **Daily Schedules and Study Groups**

#### **Table of Contents**

|                                      |   |
|--------------------------------------|---|
| Overview.....                        | 1 |
| Financial Disclosure Statements..... | 1 |
| Lecture Evaluations .....            | 1 |
| Study Groups .....                   | 2 |
| Which Study Group am I in? .....     | 2 |
| Overview of Course Schedule .....    | 3 |
| Model Daily Schedule.....            | 4 |
| Time .....                           | 4 |
| Activity .....                       | 4 |
| Daily Topics.....                    | 5 |
| Week 1 .....                         | 5 |
| Week 2 .....                         | 6 |

#### **Overview**

**Tabs A – K** provide the schedules for the lectures and Study Groups. Besides listing the theme for the day and the lectures, we are providing reprints of required readings for each lecture. In some instances, we are also suggesting additional readings for future reference. (See Tab 6 for a complete bibliography. Reprints of *Required Readings* are provided at Tab 2, immediately following the associated lecture schedule. Reprints of some *suggested reading* are provided at Tab 6 in alphabetical order by author.)

#### **Financial Disclosure Statements**

In accordance with the policies of the Accreditation Council for Continuing Medical Education and of the American Psychological Association, we are providing disclosure statements of speakers' financial interests in or relationships with the manufacturer(s) of any commercial product(s) that may be discussed during the course. Please review these in advance of each lecture. They may be found at **Tab 3, B**.

#### **Lecture Evaluations**

Please complete and hand in the **Lecture Evaluation Forms** for the daily presentations either immediately following the lecture or at the end of the day. You will find the forms in this Resource Binder for each day's schedule at Tab 2, A-K.

At the end of the course, please complete the **Overall Course Evaluation Form**, which you can find at Tab 1. (See the Table of Contents for Tab 1).

## Daily Schedules and Study Groups

### Study Groups

Except as noted, we will divide into five Study Groups to discuss the daily themes, lectures, and readings as well as to eventually design RCTs! Please note to which Study Group you have been assigned. During the first week of the course, the Study Groups will discuss issues and work on assignments associated with the daily lectures. During the second week, each Study Group will be assigned a topic on which to design a RCT. The Study Groups will present their designs for discussion and friendly critique on August 8<sup>th</sup> and 9<sup>th</sup>.

### Which Study Group am I in?

#### Group 1

Steven Ames  
Stacy Kaltman  
Maria Aranda  
Golda Ginsburg  
Catherine Davis  
Kristin Corazzini Gomez

*Location:* Jefferson Room

*Faculty:*

Week 1: Lynda Powell  
Baruch Brody

Week 2: Nancy Frasure-Smith  
Ronald Abeles

#### Group 2

Melina Aldorfer  
Steven Rothschild  
Bonnie Gance-Cleveland  
Monica Johnson-Mitchell  
Jackie Gollan  
Nadine Revheim

*Location:* West Room

*Faculty:*

Week 1: Michael Proschan  
Frank Keefe

Week 2: Robert Kaplan

#### Group 3

Rhonda Boyd  
Melicia Whitt  
Matthew Allison  
Sherry Pagoto  
Bettina Beech  
Michael Kennedy  
Anita Fernander

*Location:* South Room

*Faculty:*

Week 1: Sheryl Kelsey  
Ronald Abeles

Week 2: Nancy Houston-Miller  
Peter Kaufmann

#### Group 4

Kristin Vickers  
Denise Chavira  
Olga Bazhenova  
Moiria Rynn  
Julie Locher  
Mary Cooley  
James Carmody

*Location:* Board Room

*Faculty:*

Week 1: Janet Wittes  
Peter Kaufmann

Week 2: Sherry Willis  
Michael Proschan

#### Group 5

Jill Bennet  
Michael de Arellano  
Denise Bonds  
Risa Weisberg  
Isabel Scarinci  
Kimberly Lochner

*Location:* Studio Room

*Faculty:*

Week 1: Karina Davidson

Week 2: Nina Schooler  
Janet Wittes

Summer Training Institute for Randomized Clinical Trials  
Involving Behavioral Interventions, 2002

| Overview of Course Schedule                           |                            |   |
|---|----------------------------|---|
| Tab   | Date                       | Theme   |
| A   | July 28<br>Sunday Evening  | Welcome and Orientation                           |
| B   | July 29 Monday             | History and Methods of RCTs                       |
| C   | July 30 Tuesday            | Research Designs                                  |
| D   | July 31 Wednesday          | Designing RCTs                                    |
| E   | August 1 Thursday          | Research Ethics                                   |
| F   | August 2 Friday            | Defining and Selecting Participants               |
| <i>August 3 – 4 (Saturday and Sunday): Recreation</i> |                            |   |
| G   | August 4<br>Sunday Evening | Getting a Research Grant from the NIH             |
| H   | August 5 Monday            | Psychological Assessment, Fidelity, and Adherence |
| I   | August 6 Tuesday           | Quality Control                                   |
| J   | August 7 Wednesday         | Multi-center RCTs                                 |
| K   | August 8 Thursday          | Presentations by Study Groups<br>Graduation Party |
|   | August 9 Friday            | Presentations by Study Groups<br>Farewell         |

## Daily Schedules and Study Groups

### Model Daily Schedule

Unless otherwise noted, we will schedule the lectures, breaks, and discussion groups following this time plan. **Warning:** Subject to frequent, last minute changes!

| Time                | Activity                                    |
|---------------------|---|
| 7:00 – 8:00 AM      | Breakfast                                   |
| 8:00 – 9:00 AM      | Lecture 1                                   |
| 9:00 – 9:20 AM      | Discussion: Questions and Answers           |
| 9:20 – 9:30 AM      | Refreshment Break                           |
| 9:30 – 10:30 AM     | Lecture 2                                   |
| 10:30 – 10:50 AM    | Discussion: Questions and Answers           |
| 10:50 – 11:00 AM    | Break                                       |
| 11:00 AM – 12:00 PM | Lecture 3                                   |
| 12:00 – 12:20 PM    | Discussion: Questions and Answers           |
| 12:20 – 1:30 PM     | Lunch                                       |
| 1:30 – 3:30 PM      | Study Groups                                |
| 3:30 – 6:00 PM      | Free Time                                   |
| 6:00 – 7:00 PM      | Dinner                                      |
| 7:00 – 8:00 PM      | Occasional / Optional Lecture or Discussion |

Summer Institute for Randomized Clinical Trials  
Involving Behavioral Interventions, 2002

## Daily Topics

### Week 1

|                             |  |                                 |
|-----------------------------|--|---------------------------------|
| Tab A<br>July 28, Sunday    | Welcome and Introductions  | Ronald Abeles<br>Peter Kaufmann |
| Tab B<br>July 29, Monday    | History & Philosophy of RCTs   | Lynda Powell                    |
|                             | Hypothesis Specification   | Michael Proschan                |
|                             | Basic Study Design   | Sheryl Kelsey                   |
| Tab C<br>July 30, Tuesday   | Study Populations;<br>Randomization, and Unit of Randomization         | Sheryl Kelsey                   |
|                             | Sample Size  | Janet Wittes                    |
|                             | External & Internal Validity<br>(Effectiveness vs. Efficacy)           | Karina Davidson                 |
|                             | A Case Study<br>(Evening Discussion)                                   |                                 |
| Tab D<br>July 31, Wednesday | Control Groups,<br>Blindness/Masking,<br>Behavioral "Placebo"          | Frank Keefe                     |
|                             | Selecting Treatment and<br>Maintaining Fidelity                        | Karina Davidson                 |
|                             | Emerging Topics  | Faculty & Fellows               |
| Tab E<br>August 1, Thursday | Criteria for Ethically<br>Acceptable Clinical Trials                   | Baruch Brody                    |
|                             | Ethnic Consideration for<br>Inclusion of Special<br>Population in RCTs | Baruch Brody                    |
|                             | DSMBs  | Sheryl Kelsey                   |
|                             | Evening:<br>Managing Your Career                                       | Faculty panel                   |
| Tab F<br>August 2, Friday   | Recruitment and Retention  | Lynda Powell                    |
|                             | Analytic Dilemmas  | Janet Wittes                    |
|                             | Statistical Modeling   | Michael Proschan                |
| Tab G<br>August 3, Saturday | Recreation   | All                             |

## Daily Schedules and Study Groups

### Week 2

|                              |  |   |
|------------------------------|--|---|
| Tab G<br>August 4, Sunday    | Recreation<br><br>Evening Lecture:<br>Applying for NIH Grants                | All<br><br>Ronald Abeles                |
| Tab H<br>August 5, Monday    | Defining and Selecting<br>Participants (inclusion and<br>exclusion criteria) | Nina Schooler &<br>Sherry Willis        |
|                              | Linking Hypotheses,<br>Outcomes, and<br>Assessments                          | Nina Schooler                           |
|                              | Quality of Life  | Robert Kaplan                           |
| Tab I<br>August 6, Tuesday   | Treatment Adherence by<br>Participants                                       | Nancy Houston-Miller &<br>Sherry Willis |
|                              | Cost-effectiveness   | Robert Kaplan                           |
|                              | Emerging Topics  | Faculty & Fellows                       |
|                              | Optional Evening Lecture:<br>Meta-analysis                                   | Michael Proschan                        |
| Tab J<br>August 7, Wednesday | Missing Data   | Janet Wittes                            |
|                              | Survival Analysis  | Michael Proschan                        |
|                              | Subgroup Analysis  | Nancy Frasure-Smith                     |
| Tab K<br>August 8, Thursday  | Study Group Reports<br>Graduation Celebration                                | Fellows                                 |
| Tab K<br>August 9, Friday    | Study Group Reports<br>Adjournment   | Fellows                                 |

Tab A  
July 28, 2002  
Welcome and Introductions

|                |  |  |
|----------------|--|--|
| 1:00 PM        | Arrival and registration   | Lobby  |
| 6:00 – 7:30 PM | Dinner   | Main dinning room  |
| 7:30 – 9:00 PM | <b>Welcome and Orientation</b><br>Introduction, Goals, and<br>Issues | <b>Jefferson Room</b><br>Ronald Abeles and<br>Peter Kaufmann |
|                | <b>Issues in Behavioral RCTs</b>                                     | Peter Kaufmann   |





# Welcome and Introductions

## Rating of Individual Presentations

|   |   |   |   |  |   |    |  |
|---|---|---|---|--|---|----|--|
| Scale: 1 = Poor<br>2 = Below Average<br>3 = Average<br>4 = Above Average<br>5 = Excellent<br>NA= Not applicable |   |   |   |  |   |    |  |
| <b>Criteria</b>   |   |   |   | <b>Comments</b><br>(Use back of page as necessary) |   |    |  |
| Content   | 1 | 2 | 3 | 4  | 5 | NA |  |
| Audio-visuals   | 1 | 2 | 3 | 4  | 5 | NA |  |
| Knowledge and expertise   | 1 | 2 | 3 | 4  | 5 | NA |  |
| Teaching ability  | 1 | 2 | 3 | 4  | 5 | NA |  |



Tab B  
Monday, July 29, 2002

History and Issues in RCTs

|                 |  |                  |
|-----------------|--|------------------|
| 29 July, Monday | <b>Lecture 1: History &amp; Philosophy of RCTs</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 1</li> </ul>  | Lynda Powell     |
|                 | <b>Lecture 2: Hypothesis specification: primary/secondary outcomes.</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 2</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>• Preliminary report: effect of encainide and flecainide on mortality in a randomized trial of arrhythmia suppression after myocardial infarction. The Cardiac Arrhythmia Suppression Trial (CAST) Investigators. <i>N Engl J Med.</i> 1989 Aug 10; 321(6): 406-12</li> </ul> | Michael Proschan |
|                 | <b>Lecture 3: Basic Study Design</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Chapters 2 and. 4</li> </ul>  | Sheryl Kelsey    |



History and Issues in RCTs

**Rating of Individual Presentations**

**Lynda Powell**  
**History and Philosophy of RCTs**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



History and Issues in RCTs

**Rating of Individual Presentations**

**Michael Proschan**

**Hypothesis Specification: Primary/Secondary outcomes**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Tab B  
Monday, July 29, 2002

History and Issues in RCTs

## Rating of Individual Presentations

**Sheryl Kelsey**  
**Basic Study Design**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Tab C  
Tuesday, July 30, 2002  
Samples and Populations

|                 |  |                 |
|-----------------|--|-----------------|
| 30 Jul, Tuesday | <b>Lecture 1: Study population; randomization; unit of randomization</b><br><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Chapters 3 &amp; 5.</li> </ul>  | Sheryl Kelsey   |
|                 | <b>Sample size</b><br><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Ch 7</li> <li>• J. Wittes, Sample Size Calculations for Randomized Controlled Trials, <i>Epidemiologic Reviews</i>, 2002: 24(1), 39-53</li> </ul>   | Janet Wittes    |
|                 | <b>Lecture 3: External and internal validity</b><br><br><i>Required</i> <ul style="list-style-type: none"> <li>• Slack, M. K. &amp; Draugalis, J. R., Establishing the internal and external validity of experimental studies. <i>American Journal of Health-Systems Pharm.</i>, 2001, 58, 2173-2184.</li> <li>• Glasgow, R. E., Vogt, T. M., &amp; Boles, S. M. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. <i>American Journal of Public Health</i>, 1999, 89, 1322-1327.</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>• Miklowitz, D. J., Clarkin, J.F. Balancing internal and external validity. <i>Prevention &amp; Treatment</i>, 1999, 2, (<a href="http://www.journals.apa.org/prevention/volume2/toc-mar21-99.html">http://www.journals.apa.org/prevention/volume2/toc-mar21-99.html</a>)</li> <li>• Persons, J. B. &amp; Silberschatz, G. Are results of randomized controlled trials useful to psychotherapists? <i>Journal of Consulting and Clinical Psychology</i>, 1998, 66, 126-135.</li> </ul> | Karina Davidson |

Tab L: August 10, 2001

|  |   |     |
|--|---|-----|
|  | <b>Evening Session: A Case Study</b><br><i>Required</i> <ul style="list-style-type: none"><li>• L. Rosa, <i>et al.</i>, A close look at therapeutic touch, <i>JAMA</i>, April 1, 1998, 279(13): 1005-1010</li><li>• An Even Closer Look at Therapeutic Touch: Letters to the Editor, <i>JAMA</i>, December 9, 1998, 279(22): 1905-1908.</li></ul> | All |
|--|---|-----|





Samples and Populations

**Rating of Individual Presentations**

**Janet Wittes**  
**Sample Size**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Samples and Populations

**Rating of Individual Presentations**

**Karina Davidson**  
**External and Internal Validity**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Samples and Populations

**Rating of Individual Presentations**

**Group Discussion**

**A Case Study: A Closer Look at Therapeutic Touch**

|  |  |                    |  |
|--|--|--------------------|--|
| Scale: 1 = Poor                              |  | 4 = Above Average  |  |
| 2 = Below Average                            |  | 5 = Excellent      |  |
| 3 = Average                                  |  | NA= Not applicable |  |
| <b>Criteria</b>                              | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                                      | 1 2 3 4 5 NA                                       |                    |  |
| Usefulness in illustrating RCT design issues | 1 2 3 4 5 NA                                       |                    |  |
| Quality of discussion                        | 1 2 3 4 5 NA                                       |                    |  |
| Success as a teaching devise                 | 1 2 3 4 5 NA                                       |                    |  |



Tab D  
Wednesday, July 31, 2002

Treatment and Control Groups

|                   |   |                     |
|-------------------|---|---------------------|
| 31 Jul, Wednesday | <b>Lecture 1: Control groups, blindness/masking, behavioral “placebo.”</b><br><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 6</li> <li>• Hrobjartsson A and Gotzsche PC, Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment, <i>NEJM</i>, 2001, 344: 1594-602</li> <li>• Turner JA, et al., The importance of placebo effects in pain treatment and research, <i>JAMA</i>, 1994, 271: 1609-14</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>• Beecher, HK, The powerful placebo, <i>JAMA</i>, 1955, 27: 1602-6</li> </ul> | Frank Keefe         |
|                   | <b>Lecture 2: Selecting treatments and maintaining fidelity</b><br><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 10</li> <li>• Lichstein, K. L., Riedel, B. W., &amp; Grieve, R. (1994). Fair test of clinical trials: A treatment implementation model. <i>Advanced Behavioral Research Therapy</i>, 1994, 16, 1-29.</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>• Moncher, F. J. &amp; Prinz, R. J. Treatment fidelity in outcome studies. <i>Clinical Psychology Review</i>, 1991, 11, 247-266.</li> </ul>   | Karina Davidson     |
|                   | <b>Lecture 3: Emerging Topics</b>   | Faculty and Fellows |



Tab D  
Wednesday, July 31, 2002

Treatment and Control Groups

## Rating of Individual Presentations

### Frank Keefe Control Groups

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Tab D  
Wednesday, July 31, 2002

Treatment and Control Groups

## Rating of Individual Presentations

### Karina Davidson Selecting Treatments

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Tab D  
Wednesday, July 31, 2002

Treatment and Control Groups

## Rating of Individual Presentations

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Fill in name(s)

### Emerging Topics

|   |  |                    |  |
|---|--|--------------------|--|
| Scale: 1 = Poor                         |  | 4 = Above Average  |  |
| 2 = Below Average                       |  | 5 = Excellent      |  |
| 3 = Average                             |  | NA= Not applicable |  |
| <b>Criteria</b>                         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content            1 2 3 4 5 NA         |  |                    |  |
| Audio-visuals    1 2 3 4 5 NA           |  |                    |  |
| Knowledge and expertise<br>1 2 3 4 5 NA |  |                    |  |
| Teaching ability<br>1 2 3 4 5 NA        |  |                    |  |



Tab E  
Thursday, August 1, 2002

Ethical Issues in RCTs

|                 |  |               |
|-----------------|--|---------------|
| 1 Aug, Thursday | <b>Criteria for Ethically Acceptable Clinical Trials</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, April 18, 1979 (Department of Health, Education, and Welfare)</li> <li>• Code of Federal Regulations, Title 45, Part 46, Subpart A, Protection of Human Subjects.</li> </ul>  | Baruch Brody  |
|                 | <b>Inclusion and Exclusion in Clinical Trials: Special Populations</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• National Institutes of Health Policy and Guidelines for the Inclusion of Children as Participants in Research Involving Human Subjects, March 6, 1998.</li> <li>• National Institutes of Health Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, March 18, 1994</li> </ul> | Baruch Brody  |
|                 | <b>Lecture 3: DSMBs: Composition, functions</b><br><i>Required</i> <ul style="list-style-type: none"> <li>• Textbook, Chapters. 11 and 15</li> <li>• Wittes J., Data safety monitoring boards: A brief introduction. <i>Biopharmaceutical Report</i>, 2000, 8(1): 1-11.</li> </ul>   | Sheryl Kelsey |
|                 | <b>Evening Panel: Career Management</b>  | All Faculty   |



Ethical Issues in RCTs

**Rating of Individual Presentations**

**Baruch Brody**  
**Criteria for Ethically Acceptable Clinical Trials**

|   |  |                    |  |
|---|--|--------------------|--|
| Scale: 1 = Poor                         |  | 4 = Above Average  |  |
| 2 = Below Average                       |  | 5 = Excellent      |  |
| 3 = Average                             |  | NA= Not applicable |  |
| <b>Criteria</b>                         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content            1 2 3 4 5 NA         |  |                    |  |
| Audio-visuals    1 2 3 4 5 NA           |  |                    |  |
| Knowledge and expertise<br>1 2 3 4 5 NA |  |                    |  |
| Teaching ability<br>1 2 3 4 5 NA        |  |                    |  |





Ethical Issues in RCTs

**Rating of Individual Presentations**

**Baruch Brody**

**Ethnic Consideration for Inclusion of Special Population in RCTs**

|   |  |                    |  |
|---|--|--------------------|--|
| Scale: 1 = Poor                         |  | 4 = Above Average  |  |
| 2 = Below Average                       |  | 5 = Excellent      |  |
| 3 = Average                             |  | NA= Not applicable |  |
| <b>Criteria</b>                         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content            1 2 3 4 5 NA         |  |                    |  |
| Audio-visuals    1 2 3 4 5 NA           |  |                    |  |
| Knowledge and expertise<br>1 2 3 4 5 NA |  |                    |  |
| Teaching ability<br>1 2 3 4 5 NA        |  |                    |  |



Ethical Issues in RCTs

**Rating of Individual Presentations**

**Sheryl Kelsey  
Data Safety Monitoring Boards (DSMB)**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Tab F  
Friday, August 2, 2002  
Recruitment and Analysis

|               |  |                  |
|---------------|--|------------------|
| 2 Aug, Friday | <b>Recruitment and Retention of Participants</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Textbook, Ch. 9 &amp; 13</li> </ul>   | Lynda Powell     |
|               | <b>Analytic Dilemmas</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Textbook, Ch. 5 &amp; 16</li> <li>Yusuf, S., <i>et al.</i>, Analysis and interpretation of treatment effects in subgroups of patients in randomized clinical trials, <i>JAMA</i>, 1991, 266 (1), 93-99.</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>Lavori, P. W., Dawson R. Designing for intent-to-treat. <i>Drug Info J.</i>, 2001, 35:1079-1086</li> <li>Lavori P.W., Clinical trials in psychiatry: should protocol deviation censor patient data? <i>Neuropsychopharmacology</i>, 1992, 6:39-47</li> </ul> | Janet Wittes     |
|               | <b>Statistical Modeling; covariate adjustment</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Textbook, pp. 297-304</li> </ul>   | Michael Proschan |



Recruitment and Analysis

**Rating of Individual Presentations**

**Lynda Powell**  
**Recruitment and Retention**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Tab F  
Friday, August 2, 2002

Recruitment and Analysis

**Rating of Individual Presentations**

**Janet Wittes  
Analytic Dilemmas**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Recruitment and Analysis

**Rating of Individual Presentations**

**Michael Proshan  
Statistical Modeling**

|   |  |
|---|--|
| Scale: 1 = Poor                      4 = Above Average<br>2 = Below Average            5 = Excellent<br>3 = Average                    NA= Not applicable |  |
| <b>Criteria</b>   | <b>Comments</b><br>(Use back of page as necessary) |
| Content                    1 2 3 4 5 NA   |  |
| Audio-visuals        1 2 3 4 5 NA   |  |
| Knowledge and expertise<br>1 2 3 4 5 NA   |  |
| Teaching ability<br>1 2 3 4 5 NA  |  |



Tab G  
Saturday and Sunday, August 3 - 4, 2002  
Recreation and Grant Writing Strategies

|                          |                                  |               |
|--------------------------|----------------------------------|---------------|
| 3 – 4 Aug, Sat &<br>Sun  | <b>Recreation</b>                | See Tab 5.    |
| 4 Aug, Sunday<br>Evening | <b>Applying for an NIH Grant</b> | Ronald Abeles |



Tab G  
 Saturday and Sunday, August 3 - 4, 2002  
 Recreation and Grant Writing Strategies

## Rating of Individual Presentations

### Ronald Abeles Applying for NIH Grants

| Scale: 1 = Poor                      4 = Above Average<br>2 = Below Average           5 = Excellent<br>3 = Average                   NA= Not applicable |  |
|---|--|
| <b>Criteria</b>   | <b>Comments</b><br>(Use back of page as necessary) |
| Content                    1   2   3   4   5   NA   |  |
| Audio-visuals        1   2   3   4   5   NA   |  |
| Knowledge and expertise<br>1   2   3   4   5   NA   |  |
| Teaching ability<br>1   2   3   4   5   NA  |  |





Participants, Hypotheses, and Outcomes

|               |   |                                 |
|---------------|---|---------------------------------|
| 5 Aug, Monday | <p><b>Lecture 1: Defining &amp; selecting participants; eligibility (inclusion/exclusion criteria)</b></p> <p><i>Required</i></p> <ul style="list-style-type: none"> <li>• Textbook, Ch. 9</li> <li>• Meinert C. L. <i>Clinical Trials: Design, Conduct and Analysis</i>. New York, NY: Oxford University Press, 1986, Chapter 14, pp. 149-158.</li> </ul> <p><i>Suggested</i></p> <ul style="list-style-type: none"> <li>• Textbook, Ch. 4</li> </ul>  | Nina Schooler and Sherry Willis |
|               | <p><b>Lecture 2: Linking hypotheses, outcomes, and assessment measures; hypothesis specification</b></p> <p><i>Required</i></p> <ul style="list-style-type: none"> <li>• To be announced.</li> </ul> <p><i>Suggested</i></p> <ul style="list-style-type: none"> <li>• To be announced.</li> </ul>   | Nina Schooler                   |
|               | <p><b>Lecture 3: Health-related Quality of Life</b></p> <p><i>Required</i></p> <ul style="list-style-type: none"> <li>• R. M. Kaplan, Quality of Life and Chronic Illness, in A. Christensen and M. Antoni (eds.), <i>Chronic Physical Disorders: Behavioral Medicine's Perspective</i>. Blackwell Publishing, 2002</li> <li>• Scientific Advisory Committee of the Medical Outcome Trust, Assessing health status and quality-of-life instruments, <i>Quality of Life Research</i>, 2002, 11: 193-205.</li> </ul> <p><i>Suggested</i></p> <ul style="list-style-type: none"> <li>• Textbook, Ch. 12</li> </ul> | Robert Kaplan                   |

Tab H: Monday, August 5, 2002

Tab H  
Monday, August 5, 2002

Participants, Hypotheses, and Outcomes

### Rating of Individual Presentations

#### Nina Schooler and Sherry Willis Defining and Selecting Participants

|                         |  |                    |          |
|-------------------------|--|--------------------|----------|
| Scale: 1 = Poor         |  | 4 = Above Average  |          |
| 2 = Below Average       |  | 5 = Excellent      |          |
| 3 = Average             |  | NA= Not applicable |          |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |          |
| Content                 | 1  | 2                  | 3 4 5 NA |
| Audio-visuals           | 1  | 2                  | 3 4 5 NA |
| Knowledge and expertise | 1  | 2                  | 3 4 5 NA |
| Teaching ability        | 1  | 2                  | 3 4 5 NA |



Tab H  
Monday, August 5, 2002

Participants, Hypotheses, and Outcomes

## Rating of Individual Presentations

### Nina Schooler Linking Hypotheses and Outcomes

|                         |  |                    |          |
|-------------------------|--|--------------------|----------|
| Scale: 1 = Poor         |  | 4 = Above Average  |          |
| 2 = Below Average       |  | 5 = Excellent      |          |
| 3 = Average             |  | NA= Not applicable |          |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |          |
| Content                 | 1  | 2                  | 3 4 5 NA |
| Audio-visuals           | 1  | 2                  | 3 4 5 NA |
| Knowledge and expertise | 1  | 2                  | 3 4 5 NA |
| Teaching ability        | 1  | 2                  | 3 4 5 NA |



Participants, Hypotheses, and Outcomes

**Rating of Individual Presentations**

**Robert Kaplan**  
**Health-related Quality of Life**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Adherence and Cost-effectiveness

|                |   |  |
|----------------|---|--|
| 6 Aug, Tuesday | <b>Lecture 1: Treatment Adherence by Participants</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Textbook, Ch. 9 &amp; 13</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>To be announced.</li> </ul>   | Nancy Houston-Miller and Sherry Willis |
|                | <b>Lecture 2: Cost-effectiveness</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Kaplan RM and Groessl EJ, Applications of cost-effectiveness analysis in behavioral medicine, <i>JCCP</i>, 2002, 70(3): 482-493</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>Goldman, <i>et al.</i>, The effect of risk factor reductions between 1981 and 1990 on CHD incidence, prevalence, and mortality and cost, <i>Journal of the American College of Cardiology</i>, 2001, 38(4): 1012-1017.</li> </ul>       | Robert Kaplan                          |
|                | <b>Lecture 3: Emerging Topics</b>   | Faculty and Fellows                    |
|                | <b>Optional Evening Lecture</b><br><b>Meta-analysis and integrating across RCTs</b><br><i>Required</i> <ul style="list-style-type: none"> <li>Textbook, pp. 308-317</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>Geller NL, Proschan M, Meta-analysis of clinical trials: a consumer's guide. <i>J Biopharm Stat.</i> 1996 Nov; 6(4): 377-94</li> <li>Thomson SG, Controversies in meta-analysis: the case of the trials of serum cholesterol reduction. <i>Stat Methods Med Res.</i> 1993; 2(2): 173-92</li> </ul> | Michael Proschan                       |







Adherence and Cost-effectiveness

**Rating of Individual Presentations**

**Robert Kaplan  
Cost-effectiveness**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Adherence and Cost-effectiveness

**Rating of Individual Presentations**

---

(Insert Name of Speaker)  
**Emerging Topics**

|                         |              |  |  |
|-------------------------|--------------|--|--|
| Scale: 1 = Poor         |              | 4 = Above Average                                  |  |
| 2 = Below Average       |              | 5 = Excellent                                      |  |
| 3 = Average             |              | NA= Not applicable                                 |  |
| <b>Criteria</b>         |              | <b>Comments</b><br>(Use back of page as necessary) |  |
| Content                 | 1 2 3 4 5 NA |  |  |
| Audio-visuals           | 1 2 3 4 5 NA |  |  |
| Knowledge and expertise | 1 2 3 4 5 NA |  |  |
| Teaching ability        | 1 2 3 4 5 NA |  |  |









Tab J  
Wednesday, August 7, 2002

Issues in Data Analysis

|                  |  |                   |
|------------------|--|-------------------|
| 7 Aug, Wednesday | <b>Missing Data</b><br><i>Required:</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 16</li> </ul>   | Janet Wittes      |
|                  | <b>Survival Analysis</b><br><i>Required:</i> <ul style="list-style-type: none"> <li>• Textbook, Ch. 14</li> </ul> <i>Suggested</i> <ul style="list-style-type: none"> <li>• Hulley S, Grady D, Bush T, Furberg C, Herrington D, Riggs B, Vittinghoff E. Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. Heart and Estrogen/progestin Replacement Study (HERS) Research Group. <i>JAMA</i>. 1998 Aug 19; 280 (7): 605-13</li> </ul> | Michael Proschan, |

|  |   |                     |
|--|---|---------------------|
|  | <p><b>Subgroup Analysis</b></p> <p><i>Required</i></p> <ul style="list-style-type: none"><li>• Textbook, Ch. 16, pp. 304-306</li><li>• Yusuf S, Wittes J, Probstfield J, Tyroler HA, Analysis and interpretation of treatment effects in subgroups of patients in randomized clinical trials, <i>JAMA</i>, 1991; 266(1): 93-98.</li></ul> <p><i>Suggested</i></p> <ul style="list-style-type: none"><li>• Buyse ME, Analysis of clinical trial outcomes: Some comments on subgroup analyses. <i>Control Clin Trials</i>, 1989; 10: 187s-194s</li><li>• Furberg CD, et al., Subgroup interaction in the Heart and Estrogen/Progestin Replacement Study: Lessons Learned. <i>Circulation</i>, 2002; 105: 917-922.</li><li>• Oxman AD, Guyatt GH. A consumer's guide to subgroup analysis, <i>Ann Intern Med</i>, 1992 A.D.; 116(1): 78-84</li></ul> | Nancy Frasura-Smith |
|--|---|---------------------|

Issues in Data Analysis

**Rating of Individual Presentations**

**Janet Wittes**  
**Missing Data**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |



Issues in Data Analysis

**Rating of Individual Presentations**

**Michael Proschan  
Survival Analysis**

|                         |  |                    |  |
|-------------------------|--|--------------------|--|
| Scale: 1 = Poor         |  | 4 = Above Average  |  |
| 2 = Below Average       |  | 5 = Excellent      |  |
| 3 = Average             |  | NA= Not applicable |  |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |  |
| Content                 | 1 2 3 4 5 NA                                       |                    |  |
| Audio-visuals           | 1 2 3 4 5 NA                                       |                    |  |
| Knowledge and expertise | 1 2 3 4 5 NA                                       |                    |  |
| Teaching ability        | 1 2 3 4 5 NA                                       |                    |  |





Issues in Data Analysis

**Rating of Individual Presentations**

**Nancy Frasure-Smith  
Subgroup Analysis**

|                         |  |                    |          |
|-------------------------|--|--------------------|----------|
| Scale: 1 = Poor         |  | 4 = Above Average  |          |
| 2 = Below Average       |  | 5 = Excellent      |          |
| 3 = Average             |  | NA= Not applicable |          |
| <b>Criteria</b>         | <b>Comments</b><br>(Use back of page as necessary) |                    |          |
| Content                 | 1  | 2                  | 3 4 5 NA |
| Audio-visuals           | 1  | 2                  | 3 4 5 NA |
| Knowledge and expertise | 1  | 2                  | 3 4 5 NA |
| Teaching ability        | 1  | 2                  | 3 4 5 NA |



Tab K  
Thursday and Friday, August 8-9, 2002

Study Groups

|                 |   |     |
|-----------------|---|-----|
| 8 Aug, Thursday | <b>Study Group reports on RCT designs</b><br><b>Evening: Graduation dinner and ceremony</b> | All |
| 9 Aug, Friday   | <b>Study Group Reports on RCT designs</b><br><b>~1:00 PM    Adjournment</b>                 | All |